K072691

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JAN 31 2008

**September 21, 2007**

# 510(k) Summary

**Submitter's Name and Address:**

STI Medical Systems
733 Bishop St. Suite 3100
Honolulu, HI 96813

**Contact Person and Telephone Number:**

Rolf Wolters, Ph.D.
VP of Programs/Product Management
(808) 540-4728

| | |
|---|---|
| **Trade/Proprietary Name:** | Cervical MD™ |
| **Common/Usual Name:** | Digital Colposcope |
| **Classification Name:** | Colposcope |
| **Classification Regulation:** | 21 CFR 884.1630 |
| **Device Class:** | Class II |
| **Product Code:** | HEX |
| **Advisory Panel:** | Obstetrics/Gynecology |
| **Predicate Device:** | Welch Allen Video Colposcope Model 88000 (K955635) |

**Device Description:**

*Cervical MD* is a digital colposcope designed to acquire images of the vagina, cervix and external genitalia. It is used to diagnose abnormalities and select areas for biopsy. The illumination and optical design of the device allow the user to capture high resolution quality images. The optical subsystem is augmented by integrated image quality assessment algorithms ensuring that focused, centered and balanced-contrast images are acquired. A liquid crystal display (LCD) provides a video display and user interface information. The acquired images can be transferred to a computer and viewed on a monitor.

*Cervical MD* is substantially equivalent to the Welch Allyn Video Colposcope (K955635). Both devices have the same intended use. Both incorporate illumination, power and video into stand-alone units. They provide image capture

functions at the same working distance and provide a means of displaying the digital image on a video screen and record pictures of the examination area.

Both devices have focusing, magnification and green filter capabilities however the software contained in each device has slightly different technological characteristics. *Cervical MD* contains software that indicates when quality (focused, centered and balanced contrast) imagery has been acquired. *Cervical MD* has image polarization capabilities the predicate device does not. None of the software-managed features presents any new risks or hazards and are only provided to enhance the acquisition and analysis of the image in real time.

**Indications for Use:**

*Cervical MD* is a digital colposcope designed to acquire images of the vagina, cervix and external genitalia. It is used to diagnose abnormalities and select areas for biopsy.

**Performance Testing:**

Design verification testing has been conducted to verify that the device satisfies the performance requirements of the device specification and that the device performance is equivalent to the predicate device in relevant areas of comparison.

**Conclusion:**

The STI *Cervical MD* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Mr. Rolf Wolters
Vice President/Program Management
Science and Technology International® (sti)
733 Bishop Street
Makai Tower, Suite 3100
HONOLULU HAWAII 96813

Re: K072691
Trade/Device Name: Cervical MD™ (Model C10)
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: January 14, 2008
Received: January 16, 2008

Dear Mr. Wolters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# 4 Indication for Use Statement

**510(k) Number (if known):** K072691

**Device Name:** Cervical MD™ (Model C10)

**Indications for Use:** Cervical MD™ is a digital colposcope designed to acquire images of the vagina, cervix and external genitalia. It is used to diagnose abnormalities and select areas for biopsy.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072691